

Date of Approval: October 15, 2014

# FREEDOM OF INFORMATION SUMMARY

## ORIGINAL ABBREVIATED NEW ANIMAL DRUG APPLICATION

ANADA 200-522

Carprofen Sterile Injectable Solution

carprofen

Dogs

For the relief of pain and inflammation associated with osteoarthritis and for the control of postoperative pain associated with soft tissue and orthopedic surgeries in dogs

Sponsored by:

Putney, Inc.

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I. General Information:

A. File Number

ANADA 200-522

B. Sponsor

Putney, Inc.  
One Monument Sq.  
Suite 400  
Portland, ME 04101

Drug Labeler Code: 026637

C. Proprietary Name

Carprofen Sterile Injectable Solution

D. Established Name

carprofen

E. Pharmacological Category

Non-steroidal anti-inflammatory drug

F. Dosage Form:

Injectable Solution

G. Amount of Active Ingredient

50 mg/mL

H. How Supplied

20 mL, glass, sterile, multi-dose vials

I. Dispensing Status

Rx

J. Dosage Regimen

The recommended dosage for subcutaneous administration to dogs is 2 mg/lb (4.4 mg/kg) of body weight daily. The total daily dose may be administered as either 2 mg/lb of body weight once daily or divided and administered as 1 mg/lb (2.2 mg/kg) twice daily. For control of postoperative pain, administer approximately 2 hours before the procedure.

K. Route of Administration

Subcutaneous injection

## L. Species/Class

Dogs

## M. Indication

For the relief of pain and inflammation associated with osteoarthritis and for the control of postoperative pain associated with soft tissue and orthopedic surgeries in dogs.

## N. Reference Listed New Animal Drug

RIMADYL; carprofen; NADA 141-199; Zoetis Inc.

## II. BIOEQUIVALENCE:

Under the provisions of the Federal Food, Drug, and Cosmetic Act, as amended by the Generic Animal Drug and Patent Term Restoration Act of 1988, an abbreviated new animal drug application (ANADA) may be submitted for a generic version of an approved new animal drug (reference listed new animal drug). New target animal safety and effectiveness data and human food safety data (other than tissue residue data) are not required for approval of an ANADA.

Ordinarily, the ANADA sponsor is required to show that the generic product is bioequivalent to the reference listed new animal drug (RLNAD), which has been shown to be safe and effective. If bioequivalence is demonstrated through a clinical endpoint study, then a tissue residue study to establish the withdrawal time for the generic product should also be conducted. For certain dosage forms, the agency will grant a waiver from the requirement of demonstrating bioequivalence (55 FR 24645, June 18, 1990; Fifth GADPTRA Policy Letter; Bioequivalence Guideline, October 9, 2002).

Based on the formulation characteristics of the generic product, Putney, Inc. was granted a waiver from the requirement to demonstrate bioequivalence for the generic product Carprofen Sterile Injectable Solution (carprofen). The generic product is administered as an injectable solution, contains the same active ingredient in the same concentration and dosage form as the RLNAD, and contains no inactive ingredients that may significantly affect the bioavailability of the active ingredient. The RLNAD is RIMADYL (carprofen) injectable solution, and was approved for use in dogs on March 3, 2003.

## III. EFFECTIVENESS:

CVM did not require effectiveness studies for this approval.

## IV. TARGET ANIMAL SAFETY:

CVM did not require target animal safety studies for this approval.

## V. HUMAN FOOD SAFETY:

Data on human food safety, pertaining to drug residues in food, were not required for approval of this application. This drug is approved for use in dogs, which are not food producing animals.

VI. USER SAFETY:

The product labeling contains the following information regarding safety to humans handling, administering, or exposed to Carprofen Sterile Injectable Solution:

Keep out of reach of children. Not for human use. Consult a physician in cases of accidental human exposure. For use in dogs only.

VII. AGENCY CONCLUSIONS:

This information submitted in support of this ANADA satisfies the requirements of section 512(n) of the Federal Food, Drug, and Cosmetic Act and demonstrates that Carprofen Sterile Injectable Solution, when used according to the label, is safe and effective.